

Notice of Allowability

Application No.

10/690,800

Examiner

Gregory W. Mitchell

Applicant(s)

LAVOIE ET AL.

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1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Remarks and Amendments filed June 20, 2005.
2. ☒ The allowed claim(s) is/are 1-28.
3. ☒ The drawings filed on 21 October 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

(1) Please add the phrase "issued as U.S. Patent No. 6,667,302," following the phrase "This application is a divisional application of U.S. Patent Application Serial No.: 09/869,141," and prior to "filed on June 13, 2001, entitled ..."

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Examiner has withdrawn the 35 USC 112(1) scope of enablement rejection of claims 1-28 in view of Applicant's arguments, as set forth in the Remarks dated December 01, 2004, Dancey et al. (*British Journal of Cancer*, 74, 327-38) and Rangarajan et al. (*Bioorganic & Medicinal Chemistry*, 8, 1371-82).

Applicant argued on page 12 of the Remarks filed December 01, 2004 that topoisomerase I poisons are known to inhibit cancer cell growth. Applicant's specification indicates that the compounds claimed herein are topoisomerase I poisons. See pp. 2-3.

Dancey et al. teaches that topoisomerase I poisons are known to have broad anti-tumor activity (Abstract). Furthermore Dancey et al. teaches that cancers such as lymphomas and leukaemias are known to have significant increases in topoisomerase I and that such cells are hypersensitive to topoisomerase I poisons, such as camptothecin (p. 327, first full paragraph). Likewise, Applicant's specification indicates the cytotoxicity of compounds 2 and 3 of Figure 1 versus RPMI, lymphoblastic leukemia, and its camptothecin-resistant variant cell line CPT-K5.

Rangarajan et al. teaches compound similar to the compounds claimed herein as topoisomerase I poisons (Abstract; p. 1372). It is noted that each of the compounds tested was found to be cytotoxic versus RPMI (Table 4). The only compound wherein the cytotoxicity was found to be significantly different from the other compounds, was when X was NH (compound 4). It is noted that NH substitution of the terminal ring system is excluded from the instant claims (it is also noted that the terminal ring system is not allowed to be an indole as it is in Rangarajan et al.).

Accordingly, it is Examiner's position that the instant claims are enabled.

The closest prior art is Loewe et al. (*Arzneimittel-Forschung*, 24(12), 1927-33), which teaches the compounds disclosed therein as substances with chemotherapeutic activity. Each of the R groups disclosed therein is represented by an amine, however. In the instant claims, R₂ cannot be an amine. Accordingly, the compounds disclosed by Loewe et al. are not within the scope of the instant invention, nor do they render the

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pending claims obvious. For the closest compound, see page 1931, 7th compound from the top.

Applicant's amendments are sufficient to overcome the obviousness type double patenting rejection over USPN 6221892.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER